

## SECTION 3

Summary of Safety and Effectiveness

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Sponsor: EMcision, Ltd.

JUN 10 2009

Contact Person: Nagy Habib, MD  
Chief Executive Officer  
Liver Surgery Section, Hammersmith Hospital  
Du Cane Road  
London, W12 0NN  
United Kingdom

Summary Prepared: 2007-05-01

Trade Name: Habib EndoHPB

Common Name: Endoscopic Electrosurgical Unit

Classification: Class II per 21 CFR 876.4300

Product Code: Gastroenterology-Urology (GU)  
KNS

Predicate Device: Habib Endoblate catheter manufactured by EMcision Ltd  
(K072383.)

## Intended Use:

The Habib EndoHPB is a radiofrequency (RF) catheter which provides bipolar energy to enable the Endoscopist to cauterize and coagulate tissue in the gastrointestinal tract.

## Description:

The Habib EndoHPB is a bipolar radiofrequency (RF) device that consists of a catheter with 2 ring electrodes, introduced via an endoscope's biopsy channel and activated with bipolar RF energy.

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The Habib EndoHPB has an attached cable which connects the device to an RF Generator. The catheter is inserted into the gastrointestinal tract and the tissue is coagulated using the RF power. The Habib EndoHPB is designed for use in endoscopic procedures and is a single use sterile device.

#### Technological Differences:

The Habib EndoHPB has the same basic technological characteristics as the Habib Endoblate. Both devices use bipolar RF energy through a number of electrodes to coagulate tissue.

#### Performance Data:

Performance testing was undertaken to ensure that the Habib EndoHPB functions as intended and meets design specifications. Sufficient data was obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 10 2009

EMcision Ltd.  
% Mr. Morten Simon Christensen  
Staff Engineer & FDA Office Coordinator  
Underwriters Laboratories, Inc.  
455 East Trimble Road  
SAN JOSE CA 95131

Re: K083292

Trade/Device Name: Habib EndoHPB  
Regulation Number: 21 CFR 876.4300  
Regulation Name: Endoscopic electrosurgical unit and accessories  
Regulatory Class: II  
Product Code: KNS  
Dated: May 20, 2009  
Received: May 26, 2009

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2

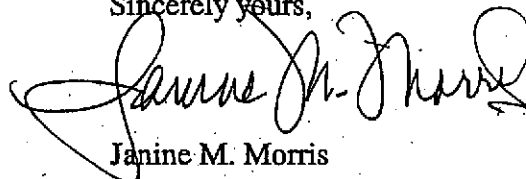
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Janine M. Morris  
Acting Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

SECTION 2  
Indications for Use Statement

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Indications For Use Statement

510(K) Number (if known)                      Not yet Allocated

Device Name                                      Habib EndoHPB

The Habib EndoHPB is intended to be used to assist in the coagulation of tissue during Endoscopic surgical procedures in the Gastro-intestinal Tract.

PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   X   OR Over the Counter Use           

(per 21 CFR 878.4400)



(Division Sign-Off)

Division of Reproductive, Abdominal and  
Radiological Devices

510(k) Number

K083292